

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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3 Applicant: MICHAEL J. JANGULA

4 Title: SYRINGE NEEDLE DE-CAPPING AND RE-CAPPING DEVICE

5 Serial No: 10/770,255

6 Filing Date: **FEBRUARY 2, 2004**

7 Group Art Unit: 3763

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INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR 1.97

In compliance with Applicant's and his attorney's duty of disclosure under 37 CFR 1.56, the Applicant does hereby submit the following Information Disclosure Statement, Form PTO - 1449, and copies of the references listed thereon.

A patent search was manually conducted for the invention described in the abovereferenced patent application. In the course of the search, no patents were found for an apparatus that has the same structural features or that operates in the same manner such as the invention listed above. The following seven (7) patents, however, were noted as being of interest and are hereby brought to the Examiner's attention as references AA - AG. The significance of each listed reference is as follows:

AA. Reference U.S. Patent No. 5,927,351 (Zhu et al.) discloses an improved drawing station system for handling radioactive material for use in syringes in the health care industry. The system includes a drawing station, a syringe shield and two different radio-pharmaceutical pigs. The drawing station has a base with a support and two arms mounted thereto to support a first radio-pharmaceutical pig enclosing a container of radioactive material. The radio-pharmaceutical pig is releasably mounted to the second arm so that the radio-pharmaceutical pig is pivotable about two predetermined axes to position the container for penetration by the syringe needle to draw radioactive material from the container into the syringe.

AB. Reference U.S. Patent No. 5,607,403 (Kretzschmar et al.) discloses a new disposable needle cap holder for safe, one-handed recapping of hypodermic syringe needles is disclosed. The needle cap holder is a generally rectangular solid having a back face with an adhesive surface so that the solid can be attached to a horizontal or vertical surface, such as a table, cart or wall. A front face on the solid has an opening for a bore that extends through the solid toward the back face. The bore is sized to hold a needle cap. A bulls-eye ring surrounds the bore opening. The back face is at an acute angle to the front face. To use, the back face is attached to a flat surface and a needle cap inserted into the bore. Using the bulls-eye ring as a guide, a healthcare worker inserts a needle into the held needle cap until it snaps into place. The needle cap holder can be made of any lightweight disposable plastic material.

AC. Reference U.S. Patent No. 5,334,151 (Santilli) discloses a device for capping and uncapping a hypodermic needle includes a body portion having an opening therein through, which the cap of a hypodermic needle may be inserted and removed. The body

portion has a base that can be attached to a surface by an adhesive layer or by hook and loop fasteners. The body portion includes a conical helix having screw threads that engage the end of the cap upon rotation of the cap therein. Because the cap is mechanically secured by the helix, the needle can be removed or inserted into the cap while the cap is retained in place. The body portion is made of an inexpensive, resilient foam material.

AD. Reference U.S. Patent No. 5,078,695 (<u>Farrar, Jr. et al.</u>) discloses a needle cap holder of a syringe. It is of compressible material, such as rubber, having a central portion tapered inwardly from the top and bottom. It has a central, vertical cylindrical opening for receiving a needle cap of the syringe. It has a concave bottom portion.

AE. Reference U.S. Patent No. 4,892,525 (Hermann, Jr. et al.) discloses the present invention relates to improvements in conventional protection barrel and cap packaging for hypodermic needles, whereby a structural guard is provided to encourage a user's fingers to locate directly behind the guard, and around the outer surface of an opening into the protected barrel. A person inserting a needle into a barrel automatically seeks to grasp the barrel proximate its open end, to avoid yawing of the barrel during the manipulative process. The present invention facilitates holding of a barrel proximate the opening, while providing, as an extension therefrom, a needle entrance guide means which extends axially and laterally therefrom. The laterally expanded barrel opening defines a transition ramp surface into the barrel open end. Accordingly, the present invention ensures that the needle will be guided into the barrel open end and towards the barrel closed end, even if the needle insertion step included an initial lateral misalignment, off the axial centerline of the barrel cap which extends the guard protections of the barrel needle barrel protector, through a cap

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which comprises an extending boss from the exterior surface of the cap, so that both needles will be guided away from accidental, manipulative stabbing. A fourth object of the present invention is to provide a protective barrel and extended cap packaging for enclosing a hypodermic needle and syringe assembly, wherein a disposable axially extending housing can be discarded, leaving a protective needle barrel to offer protection to the user, when reinserting only the barrel onto the needle.

- Reference U.S. Patent No. 4,836,373 (Goldman) discloses a device for AF. handling a hypodermic syringe and a cover, therefore has a base, a tubular body projecting from the base and having an open end for receiving a syringe cover and frictionally engaging the same. The device also has a mechanism for breaking the frictional engagement. The base has a piece of material one side of which adhesively engages the base. The other side of the piece of material has pressure sensitive material, so that the device is mountable on a plane surface. Only one hand is needed to operate the device, and a plurality of the devices can readily be arranged in an array in close proximity to each other.
- Reference U.S. Patent No. 4,393,864 (Galkin et al.) discloses the present AG. invention relates to syringe loading shields for use with syringes during the drawing of aliquots of radioactive materials from shielded vials containing same. Each syringe loading shield is provided with means for shielding radiation emanating from the mouth of the vial during the material-withdrawal, syringe loading process. In a preferred embodiment, the syringe loading shield comprises a radiation detector for detecting and calibrating the radioactive dosage of the material which is drawn into the syringe barrel. In the preferred embodiment, a substantially tubular shield having a high density viewing window recessed

therein is disclosed which is comprised of a plurality of sheaths. A novel hand shield and syringe for use with radioactive materials are also disclosed.

The Applicant and his attorney submit that the above-cited references taken alone or in combination neither anticipate nor render obvious the present invention. None of the references disclose or claim a syringe needle de-capping and re-capping device, comprising a cylindrical shaped body with longitudinally aligned cavity formed therein, said body including a finger gripping section, a removable cap selectively attachable to said body, said cap including an inward extending aligned neck, a bushing longitudinally aligned and located inside said cavity, said bushing including a cylindrical shaped void area capable of receiving said neck on said removable cap, said bushing includes a stop surface formed inside said void area, and a spring nut located inside said void area of said bushing, said spring nut including a center bore that engages the tip of a needle cap with inserted therein.

The listed references relate only to the general field of the disclosure and do not constitute an admission that the references are relevant or material to the claims; they are cited only as constituting the closest art of which the Applicant and his attorney are aware.

Respectfully submitted,

DEAN A. CRAINE

Reg. No. 33,591

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INFORMATION DISCLOSURE CITATION (Use several sheets if necessary) Applicant(s) MICHAEL J. JANGULA												
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U.S. PATENT DOCUMENTS												
	P 0 L	· · · · ·	DATE	NAME		CLASS SUBCLASS		FILING DATE IF APPROPRIATE				
AXAMINER TIAL	TRADE	5,927,351	07/27/1999	ZHU ET AL.		141	330	05/30/1997				
•	AB.	5,607,403	03/04/1997	KRETZSCHMAR ET AL.		604	263	04/05/1996				
	AC.	5,334,151	08/02/1994	SANTILLI		604 192		05/03/1993				
	AD.	5,078,695	01/07/1992	FARRAR, JR. ET AL.		604 192		05/14/1990				
	AE.	4,892,525	01/09/1990	HERMANN, JR. ET AL.		604 263		01/18/1984				
	AF.	4,836,373	06/06/1989	GOLDMAN		206 366		10/03/1988				
	AG.	4,393,864	07/19/1983	GALKIN ET AL.		128	1.1	04/27/1981				
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